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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,631	05/18/2001	Maurice Chazalet	P/3610-12	4668

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EXAMINER	
HUI, SAN MING R	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 05/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,631	CHAZALET ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 11-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 11-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendments of claims 1, 7, 14, 16-17 filed February 20, 2002 have been entered.

The cancellation of claims 8-10 in amendment filed February 20, 2002 is acknowledged. The addition of claims 19-21 in amendment filed February 20, 2002 is acknowledged.

The outstanding rejections of claims 7, 9, 16, and 17 under 35 112, second paragraph are withdrawn in view of the amendments filed February 20, 2002.

Claims 1-7 and 11-21 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 11-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the imidazolin-5-one and amino acid amide composition recited in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the instant case, there is no adequate direction provided by the applicant as to how to select the active compounds that can be successfully used in the synergistic composition and method invention.

Furthermore, the instant specification does not provide any working examples to point out how the 2-imidazolin-5-one and amino acid amide compounds may be used synergistically in the claimed antifungal methods and compositions.

Synergism is an unexpected and highly unpredictable effect. Applicant must demonstrate such an unexpected result for a representative number of compounds of the very broad genus herein (See MPEP 716.02(b)). Synergism should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to synergism (i.e., unexpected benefits) must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, such evidence to demonstrate synergism is not present.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "curatively or preventively controlling" in claim 14 renders the claim indefinite because "cure" or "prevention" are absolutes denoting a complete absence of disease processes now and in future whereas "controlling" implies merely

maintaining or reducing fungal numbers or reproduction. Therefore the intended method is not understood.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 and 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latorse (WO96/03044 provided by the applicants in Paper 5 received May 17, 2001), Shibata et al. (EP 0775 696 A1 provided by the applicants in Paper 5 received May 17, 2001), and Seitz et al. (EP 0472 996 A1 provided by the applicant in Paper 5 received May 17, 2001) in view of Budavari (Merck Index, 11th ed., 1989, monograph 4964, page 803), references of record in the previous office action mailed February 20, 2002.

Latorse teaches a composition and a method employing 2-imidazoline-5-one compounds including (4-S)-4-methyl-2-methylthio-4-phenyl-1-phenylamino-2-imidazoline-5-one useful as a fungicidal treatment for vegetables (See particularly the abstract, page 1, line 1 – page 3, line 21; also page 12, examples PM1 – PM5; page 17, example 1- page 31, example 28; also claims 1-14). Latorse also teaches the dosage of the 2-imidazoline-5-one compounds to be 10 to 5000g/ha (See claim 14).

Shibata et al. teaches a composition and a method employing valinamide-derivative compounds including N^1-[(R)-1-(6-fluoro-2-benzothiazolyl)ether]-N^2-isopropoxy-carbonyl-L-valinamide useful as a fungicidal treatment for crops (See particularly abstract, page 3, line 22 – page 5, line 57; also compound No. 4 in page 18, first paragraph; page 21- page 28, examples 1-4). Shibata et al. also teaches the effective amount of the actives to be 0.1 to 5000g to treat 10 areas in liquid formulation (See page 20, line 28-36). Shibata et al. also teaches that the active compounds may be formulated into wettable powder, emusified liquids, or granules and that the active can be sprayed on the vegetables (see page 20, line 49 – page 21, line11: formulation Examples 1-4; also page 21, example 1).

Seitz et al. teaches a valinamide-derivatives including isopropyl[2-methyl=1=(1-phenylethylcarbamoyl)-propyl]carbamte useful to be a fungicidal compound (see particularly abstract, page 8, compound 3 and page 9, compound 13).

The references do not expressly teach the combination of the 2-imidazoline-5-one compounds and valinamide-derivative compounds together in a composition and method of fungicidal application. The references do not expressly teach employment of an additional fungicidal compound, iprodione, in the composition. The references do not expressly teach the ratio between the two active compounds. The references do not expressly teach dose of the two active compounds to be 10 to 500g/ha or 20 to 300g/ha.

Budavari teaches that iprodione is useful as fungicide (See page 803, col. 2, Use Section).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the 2-imidazoline-5-one compounds and valinamide-derivative compounds, and/or iprodione together with a dosage herein and ratio herein to form a fungicidal composition.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to employ the combination fungicidal composition herein in a method to control the phytopathogenic fungi of crops.

One of ordinary skill in the art would have been motivated to combine the 2-imidazoline-5-one compounds and valinamide-derivative compounds, and/or iprodione together with a dosage herein and ratio herein to form a fungicidal composition because combining two or more agents which are known to be useful to be a fungicide individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Please note that in the instant case, 2-imidazoline-5-one compounds, valinamide-derivative compounds, and iprodione are known to be useful as fungicides individually. Therefore, they are expected to be useful together in a single fungicidal composition or method, at least additive effect would be expected. Furthermore, The optimization of result effect parameters (dosage range, ratio of the active components) is obvious as being within the skill of the artisan.

One of ordinary skill in the art would have been motivated to employ the combination fungicidal composition herein in a method to control the phytopathogenic fungi of crops because the individual compounds are known to be useful in method of fungicidal application in plants or crops. Therefore combining these components

together would have been reasonably expected to be useful in a method of doing the same. At least additive efficacy is expected. See *In re Kerkhoven* 205 USPQ 1069

Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants does not clearly and convincingly demonstrate synergism for any combination within the claims and is not reasonably commensurate in scope with the instant claims. For example, examples 1 to 4 in page 31 to 38 in the specification relate only to certain fungal species and the employment of 3 compounds useful from genus herein in a fungicidal combination in accordance with the claims (i.e., compound A, B, and C in the specification). A supraadditive effect for the combinations of individual agents herein, based on raw data on the same individual agents in comparison to their corresponding combination, is not present. Furthermore, absent claims commensurate with a showing of any unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

The declaration under 37 CFR 1.132 filed May 2, 2002 is insufficient to overcome the rejection of claims 1-18 based upon 35 USC 103 as set forth in the last Office action because: the report of Latorse and Givois is not submitted in a proper declaration form. There is no assurance in the report as to the truth of the facts presented. It is improper to file a declaration with the data in separate submissions, as it was done in the instant

case. Therefore, the report is not seen as probative evidence setting forth unexpected benefits to support patentability in the declaration under 37 CFR 1.132.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
May 15, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200